

Center for Drug Evaluation and Research - Office of Generic Drugs
Quantitative Report

Table I

ORIGINAL APPLICATIONS

	Jul-03	Aug-03	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04	Apr-04	May-04	Jun-04	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	37	36	26	38	44	102	54	25	51	40	38	40	531	44	39	36
AMENDMENTS	217	233	203	217	202	222	183	228	294	256	246	264	2765	230	255	183
- MAJOR	102	120	98	106	94	87	85	137	146	123	123	126	1347	112	124	92
- MINOR	115	113	105	111	108	135	98	91	148	133	123	138	1418	118	131	91
-- ACTIONS --																
APPROVALS	13	20	44	16	17	22	24	23	27	22	25	41	294	25	29	24
TENTATIVE APPROVALS+	7	4	14	7	5	11	8	11	10	7	7	2	93	8	5	7
APPROVABLE+	0	0	0	0	0	0	0	1	0	3	0	0	4	0	1	0
NOT APPROVABLE	65	78	52	65	69	88	66	76	86	88	83	107	923	77	93	64
REFUSE TO RECEIVE	7	2	4	9	5	1	13	13	12	4	5	6	81	7	5	5
WITHDRAWALS	6	10	3	2	7	24	19	10	5	4	7	18	115	10	10	14
- OF APPROVED	3	9	1	2	3	21	16	2	5	2	4	14	82	7	7	6
- OF UNAPPROVED	3	1	2	0	4	3	3	8	0	2	3	4	33	3	3	8
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	498	524	506	515	533	607	625	586	626	632	625	587		572	615	453
AWAITING OGD ACTION (> 180 DAYS)***	47	60	58	65	54	73	69	65	56	57	58	60		60	58	29
AWAITING OGD ACTION (< 180 DAYS)***	451	464	448	450	479	534	556	521	570	575	567	527		512	556	425

*** In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications. As of June 30, 2004, 2 original application and 0 supplements were suspended.

Upon completion of validity assessments, suspended applications may be returned to active pending status.

+ Note: Approvable and Tentative approvals are counted as approvals subsequently when approved.

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Table II

POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)

	Jul-03	Aug-03	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04	Apr-04	May-04	Jun-04	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	260	372	185	167	238	244	240	223	422	342	264	446	3403	284	351	218
AMENDMENTS TO SUPPLEMENTS	313	395	218	257	267	235	279	310	507	384	281	468	3914	326	378	279
--SUPPLEMENTAL ACTIONS--																
APPROVALS	250	342	134	390	180	170	145	231	166	209	141	282	2640	220	211	201
APPROVABLE	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
NOT APPROVABLE	84	100	68	57	66	93	86	122	79	107	89	74	1025	85	90	91
WITHDRAWALS	122	19	4	10	14	6	6	9	10	7	14	24	245	20	15	16
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1308	1285	1366	1213	1225	1298	1266	1334	1589	1719	1777	1914		1441	1803	1261
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	46	66	61	66	61	71	87	88	99	71	75	98		74	81	54
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1262	1219	1305	1147	1164	1227	1179	1246	1490	1648	1702	1816		1367	1722	1207

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Table III

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Jul-03	Aug-03	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04	Apr-04	May-04	Jun-04	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	44	49	51	66	54	42	85	68	57	57	52	62	687	57	57	51
AMENDMENTS TO SUPPLEMENTS	64	65	51	84	42	48	96	77	74	73	75	82	831	69	77	68
--SUPPLEMENTAL ACTIONS--																
APPROVALS	57	48	27	64	49	39	31	50	57	77	52	44	595	50	58	51
APPROVABLE	5	2	0	0	0	1	2	3	10	12	8	2	45	4	7	7
NOT APPROVABLE	6	8	7	3	12	11	7	9	12	10	12	4	101	8	9	10
WITHDRAWALS	5	8	6	2	5	5	1	2	3	1	3	2	43	4	2	3
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	336	343	351	357	342	345	405	407	387	354	337	363		361	351	352
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	116	118	116	127	109	125	132	131	123	107	101	100		117	103	122
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	220	225	235	230	233	220	273	276	264	247	236	263		244	249	229

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